LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES

TB Times

Shirley Fannin, M.D.
Director, Disease Control Programs

Paul T. Davidson, M.D.
Director, Tuberculosis Control Program

July 1998 Volume 10 Number 7

A Note From Dr. Davidson

Within the last few weeks the media reported that the FDA approved the first "new" drug for TB in over 25 years. This "new" drug is rifapentine, a rifamycin B derivative with a much longer half-life than rifampin, its venerable predecessor approved in 1971. The antimycobacterial spectrum is similar for both drugs. The obvious advantage of rifapentine with the longer half-life is its possible use in less frequent intermittent drug administration. Rifampin works well in intermittent treatment but must be given 3 times weekly if used from the beginning of therapy or 2 times weekly if started later in the treatment regimen *(usually somewhere between 2 and 8 weeks).* Rifapentine has had preliminary clinical studies to assess its efficacy when used once weekly during the continuation phase of treatment. The FDA approval of rifapentine is considered an "accelerated approval" for the treatment of pulmonary tuberculosis based on the 6-month follow-up data from a single clinical trial. Final approval is contingent on the results of data obtained at 24 months of follow-up. The study is a randomized trial being conducted at 29 sites in South Africa, 5 sites in the United States and 5 sites in Canada. Patients were randomized at entry to receive two months of either daily rifampin or twice weekly rifapentine together with daily isoniazid, pyrazinamide, and ethambutol. After the two months, those on rifapentine continued with once weekly isoniazid and rifapentine, and those on rifampin received twice weekly isoniazid and rifampin. At six months of follow-up, 71% of those on rifampin and 70% of those on rifapentine had successful outcomes. There were a number of factors that resulted in non-successful outcomes, including discontinuation of therapy. Relapse occurred in 8.7% of those on rifapentine and 3.9% of those on rifampin. Adverse events were infrequent and similar in both groups. Non-compliance was a significant factor in relapse, with 16% of those on rifapentine and 9% of those on rifampin being non-compliant.

Cont'd on Page 2

Conferences

TB Conferences on the first Friday of the month are held in the Andrew Norman Hall of Orthopaedic Hospital, located at Adams Blvd. & Flower Street. The Physician Case Presentations on the third Friday of the month are held at the TB Control Program Office, Room 506A. Participants must sign-in to receive applicable CME credit. Late arrivals of 15 minutes for a 1 hour program or 30 minutes for a 2 hour program will not receive CME credit.

August 7, 1998
9:00-10:15a.m.
"Medical Management of MDR-TB 1998"
Annette T. Nitta, M.D.

10:30-11:30a.m.
TB Case Presentation/Discussion
Hanh Q. Lê, M.D.

August 21, 1998
Physician Case Presentations
Hanh Q. Lê, M.D.
TB Control Classroom, #506A

ERN Quarterly Inservice

August 7, 1998, 10:30-11:30
"Strategies for Improving Patient Education - The ABCs of Adult Education"
Bob Miodovski, M.P.H.
Orthopaedic Hospital
Andrew Norman Hall

Final '98 ERN Quarterly Inservice: November 6

The Trudeau Society of Greater Los Angeles and the American Lung Association of Los Angeles County recently presented Dr. Davidson with their annual award in recognition of excellence for many years of outstanding and dedicated service promoting pulmonary medicine. ***TB Times*** *extends its congratulations to our Editor-in-Chief!*

A Note From Dr. Davidson, cont'd

An ongoing study by CDC and the Veterans Administration in the U. S. with rifapentine initially included HIV positive and negative patients. However, the relapse rate in HIV positive patients on rifapentine was unacceptable, and rifampin mono-resistance occurred. HIV positive patients are no longer being added to this study. As a consequence of reviewing and discussing the findings available, rifapentine has been given "accelerated approval" by the FDA for treatment of HIV negative patients with pulmonary tuberculosis.

What does this mean for us here in Los Angeles? Once weekly DOT during the last 4 months of treatment in HIV negative pulmonary patients appears appealing at first glance. However, the nearly 100% increase in the number of relapses as compared to what we now obtain with isoniazid and rifampin twice weekly hardly seems reasonable in our setting. In addition, the cost of rifapentine is not currently known. Admittedly, the removal of 50% of the doses of DOT over 4 months could cut administrative costs considerably outweighing any increased costs in medication. Unfortunately, rifapentine has cross-resistance with rifampin and therefore is of no help for the MDR patient. My conclusion is that, for now, rifapentine has little, if any, role for treating TB here in Los Angeles County. As more results accumulate, we will need to take another look. Perhaps rifapentine will eventually fill an important and badly needed role for shorter and directly observed preventive therapy. Perhaps certain categories of patients with tuberculosis will be clearly identified that respond to once weekly rifapentine as well as those on rifampin twice weekly. Only time will tell.

****

Definition of Homeless

Several articles in this issue of ***TB Times*** refer to the homeless. How do we define homeless? The CDC, Division of Tuberculosis Elimination has provided all jurisdictions with a definition of homeless which is to be used for all data collection. Los Angeles County TB Control uses this same definition. Those reporting to TB Control need to use the same definition in order for our data concerning homelessness to be consistent and comparable from year to year and place to place. The box labeled "Homeless Within Past Year" should be checked yes if the patient was homeless at any time during the 12 months prior to the time when the TB diagnostic evaluation was performed. A homeless person may be defined as:

Definition of Homeless, cont'd

1. An individual who lacks a fixed, regular, and adequate nighttime residence ; or
2. An individual who has a primary nighttime residence that is:

(a) A supervised publicly or privately operated shelter that provides temporary living accommodations*(including welfare hotels, congregate shelters, and transitional housing for the mentally ill)*; or

(b) An institution that provides a temporary residence for individuals intended to be institutionalized; or

(c) A public or private place not designated for, or ordinarily used as a regular sleeping accommodation for human beings.

A homeless person may also be defined as a person who has no home, e.g., is not paying rent, does not own a home and is not steadily living with relatives or friends. Another definition is a person who lacks customary and regular access to a conventional dwelling or residence. Included as homeless are persons who live on streets or in nonresidential buildings. Also included are residents of homeless shelters, shelters for battered women, welfare hotels, and single room occupancy (SRO) facilities which are not designated for permanent, long-term housing.

If you have questions about how to complete information regarding the homeless, please contact TB Control at 213-744-6160.

****

Journal Note

In 1994, the National Health Interview Survey (NIHS), an annual face to face interview survey of a sample of U.S. households (18,000-40,000 respondents) added questions about concern for and knowledge of TB. TB questions were also added to the AIDS knowledge and attitudes supplement of the survey.

Only one-third of the respondents correctly identified that TB was transmitted through the air. Certain groups (women, individuals at risk of HIV infection, those with increased education and those above the poverty level) exhibited a greater level of knowledge regarding TB transmission.

J.E. Anderson, E. Sumartojo, B. Miller. Only one third of US adults can correctly identify how tuberculosis is spread. *Int. J. Tuberculosis and Lung Dis.* 1998; 2:607-608.

There were statistically significant differences between agencies which participated in the enhanced version *(all three phases)*, and those agencies that only had the two-hour staff training *(phase one)*. The agencies receiving all three phases reported instituting an average of 2.72 changes as a result of the project, while agencies receiving only the training reported an average of 1.1 changes. This difference was statistically significant at $p < .001$. Additionally, the agencies receiving the enhanced version were more likely to report changes in bed positioning, use of fans, TB policies, use of tissues and ventilation *(all statistically significant differences).*

A TB education and prevention program for the staff of agencies serving homeless people in Los Angeles County appears to effectively increase staff knowledge and awareness of TB and to increase the number of TB risk mitigation activities engaged in by the staff.

Agencies participating in the more intensive TB education and prevention program institute, on average, a greater number of TB risk mitigation activities than agencies that participate in a simple TB education program.

Eve Rubell, M.P.H., is the Director of Education and Training at Homeless Healthcare Los Angeles. For more information regarding this article or the project, she can be reached at 213-744-0724.

****

Levofloxacin Added to DHS Formulary

Some quinolones demonstrate in vitro activity against *M. tuberculosis*, and are used to treat selected TB patients *(e.g. some patients with MDR-TB)*. Both ciprofloxacin (CIP) and ofloxacin (OFL) have been used as experimental second-line agents, and there are some clinical data demonstrating their efficacy against Mtb. Over the years, OFL replaced CIP in TB treatment regimens in Los Angeles County because of its superior bioavailability.

Levofloxacin (trade name Levaquin), the L-isomer of ofloxacin, has superior bioavailability to even OFL. Additionally, the MIC of levofloxacin (LEV) against Mtb is reportedly lower than that of OFL, and LEV appears to be tolerated even better than OFL. LEV has been added to the DHS formulary, and is intended to eventually replace OFL in usage for TB patients. For now, limited supplies of OFL will be maintained in the DHS pharmacy pending implementation of new CDC treatment guidelines for STDs.

The TB Control Program recommends that patients requiring new prescriptions for OFL be prescribed LEV instead. All requests for LEV and other second-line TB medications will require approval via the TB Special Drug Request process. It is recommended that patients on OFL 800 mg/d be given LEV 750 mg/d instead. Monthly monitoring for drug toxicity is the same for LEV as for OFL since the former is only a purified L-isomeric form of OFL. Please contact your TB Control Lead physician if you have any questions. -A.N.

****

Mobile Chest X-Ray Project Update

The Mobile Chest X-ray Project began on December 11, 1997 and performed its final screening on May 3, 1998. A total of 2,515 individuals were screened at 48 different locations throughout Los Angeles County, including cold-and-wet weather shelters, drop-in facilities and day labor pick-up sites. Twenty-seven individuals with abnormal chest x-rays were identified, 24 of whom were referred for further evaluation. Of these, three were transported to hospital emergency rooms and 21 were referred to County TB clinics for follow-up.

A total of four active TB cases were identified, two of which were smear positive. Twelve of the suspects were closed as "not TB," two were closed as "lost," and six are still open. The case rate for the screening population of this project was 159 cases per 100,000, as compared with the overall Los Angeles County 1997 case rate of 14.9 cases per 100,000 population. The majority of suspects and cases were followed by the Hollywood and Inglewood districts, in contrast to previous mobile x-ray screenings which found most suspects and cases in the Central district, particularly the skid row area.

The TB Control Program would like to thank everyone who contributed to the success of this project, particularly district staff who in so many cases made an extra effort to ensure that these high-risk patients were seen and that the referral process ran smoothly. We would also like to recognize the excellent work of our community workers assigned to the project, Jimmy Ruiz and Luther Terrell, who were present at nearly every site and continually improved the process as we went along. Thanks again to everyone involved for a job well done!! -K.K.

Homeless Health Care Los Angeles' TB Risk Mitigation Project

In response to the epidemics of homelessness, tuberculosis and HIV in Los Angeles County, Homeless Health Care Los Angeles (HHCLA), a private non-profit agency, developed a comprehensive TB prevention program for employees who work with homeless persons. For the last three years the project has been funded through Los Angeles County DHS Tuberculosis Control Program and HUD's Housing Opportunities for People with AIDS (HOPWA).

The TB Risk Mitigation Project targets staff of agencies who provide shelter, health care, drug treatment, HIV care and other services to people at risk for TB. Service providers can play a key role in preventing TB by implementing manageable changes in their agencies and by assisting the health department in early detection and effective treatment of active cases. Approximately 75 to 100 agencies are trained each year.

Project Objectives

1. Increase employee's knowledge about tuberculosis;
2. Challenge and improve staff attitudes based on misinformation and fear;
3. Increase staff skills;
4. Institute policy changes within agency operations to adopt written guidelines and implement strategies for TB prevention; and
5. Increase access to TB screening and treatment by linking shelters with public health resources.

Program Design

Phase one consists of a two-hour TB training. Shelter staff and directors are taught how to recognize the signs and symptoms of TB and are given numerous health resources to use when referring clients. A Tuberculosis Prevention Guide for Homeless Service Providers is provided to each agency.

The second phase of the project consists of a walk-through inspection of the agency to assess the risk of environmental TB transmission.

During phase three, HHCLA health educators meet with the agency director and provide and review written recommendations to reduce the spread of TB in the agency, based on inspection findings.

Project Evaluation

To assess program effectiveness, data were collected and analyzed from 98 agencies that participated in the TB Risk Mitigation project between April 1995 and May 1997.

Fifty agencies chose to participate in phase one only. An additional 48 agencies participated in the enhanced program consisting of phase one, two and three.

Prior to the project:

1. Half the agencies reported having had experience with a TB infected client.
2. 73% reported that their staff is tested for TB, however only 27% reported that they had TB policies.
3. Almost 50% reported that their staff had little to no TB knowledge; 39% reported a moderate amount of staff knowledge; and 13% reported a high level of staff knowledge.

Evaluation Results

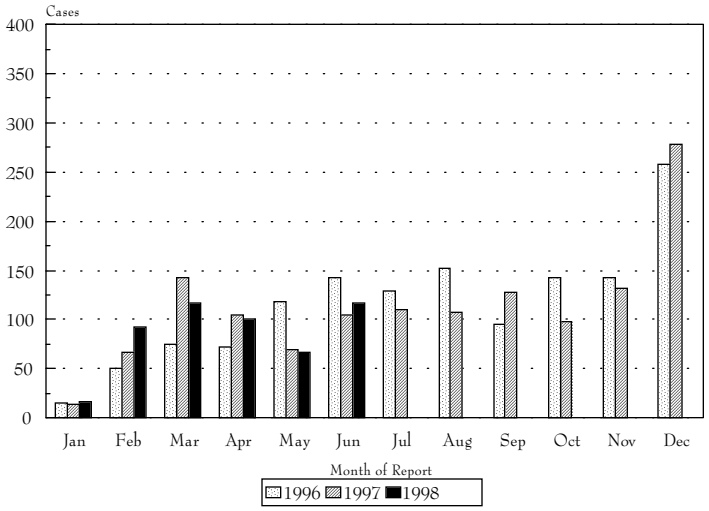
Eighty-two percent of the agencies reported making policy and/or environmental changes to reduce TB transmission risk within their facility. The changes reported include: using tissues; improving ventilation; using fans; instituting or changing policies; testing clients for TB; increasing TB awareness among staff; providing TB education; re-positioning beds and testing staff for TB.

1. 64% reported having an identified TB resource person.
2. 56% reported having had contact with their public health nurse since the training.
3. 52% reported that staff interactions with clients had changed.
4. 52% reported clients had improved access to TB screening services

The number of weekly referrals to TB services made by each facilty increased significantly ($p<.002$) from pre-training to post-training reports.

The percentage of agencies testing staff for TB on a regular basis increased from 73% prior to the project to 84% by six months after the training. Only 27% of the agencies reported having TB policies/ prevention plans in place prior to the project while 55% reported having policies in place six months after the training.

Los Angeles County Tuberculosis Control
Tuberculosis Incidence
By Month of Report, 1996-1998



TB Times Editorial Staff

Editor-in-Chief
Paul T. Davidson, M.D.
Managing Editor
Phillip L. Moore III, M.P.A.
Editorial Staff
Wendi Drummond, M.P.H., Epidemiology Analyst
Jacqueline Elliot, CDC Public Health Advisor
David Gambill, M.Sc., Program Manager

TB Times is a monthly publication to provide information to those interested in TB surveillance and TB Control Program activities. Please forward your articles, comments or suggestions to:

TB Times
Tuberculosis Control Program
2615 S. Grand Ave., Rm. 507
Los Angeles, CA 90007
Attn: Phillip L. Moore III, M.P.A.
Office: (213) 744-6160
Fax: (213) 749-0926

TB Times
County of Los Angeles
Department of Health Services
Tuberculosis Control Program
2615 S. Grand Ave., Room 507
Los Angeles, CA 90007

July Topics of Interest...

⇒ Rifapentine: New FDA Approved TB Drug!
⇒ Definition of Homeless
⇒ TB Risk Mitigation Project by Homeless Healthcare L.A.
⇒ Levofloxacin Added to DHS Formulary
⇒ Journal Note